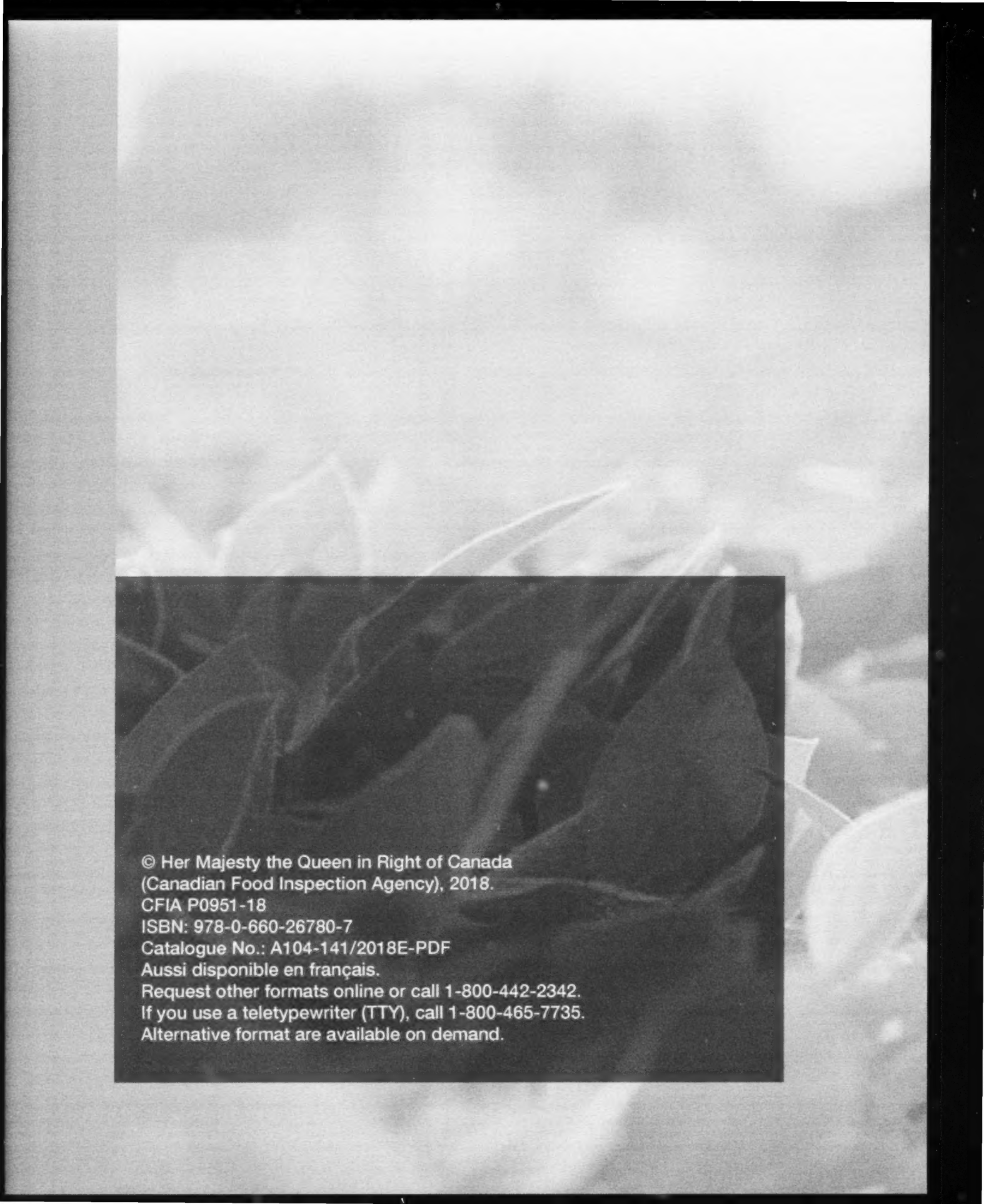
Incident Report

GENETICALLY MODIFIED WHEAT 2018

Government of Canada Gouvernement du Canada

Canada



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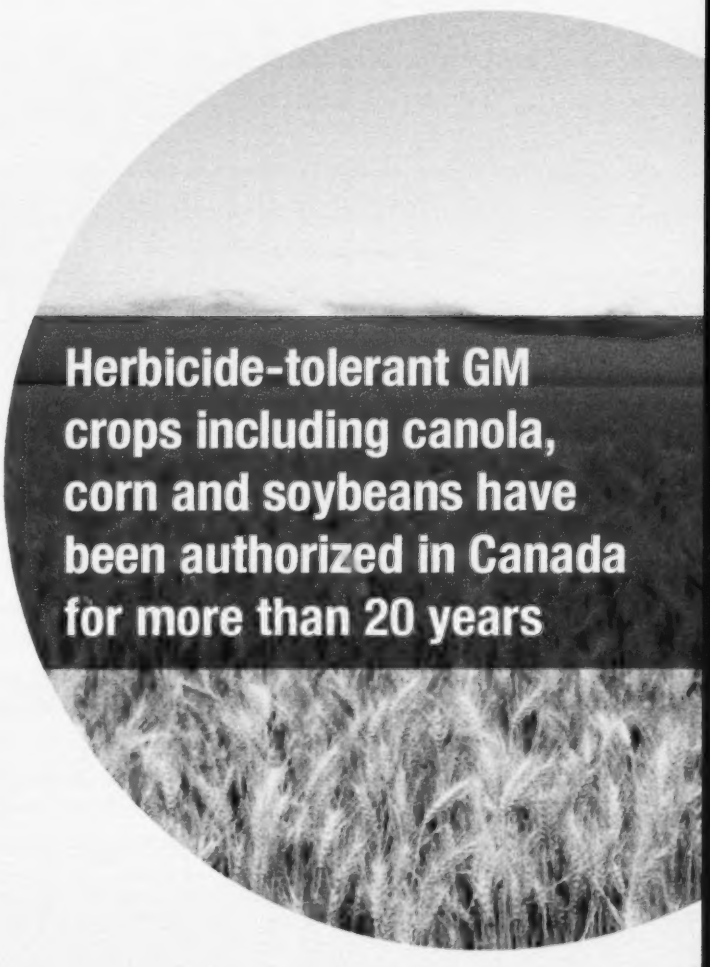
EXECUTIVE SUMMARY

- The Canadian Food Inspection Agency (CFIA) was notified on January 31, 2018, about a few wheat plants found on an access road in southern Alberta that survived a spraying treatment for weeds.
- The CFIA's tests confirmed that the wheat found is genetically modified to be herbicide tolerant. Genetically modified (GM) wheat is not authorized to be grown commercially in any country.
- Since being notified, the CFIA worked diligently with federal and provincial partners and other stakeholders to determine the origin and extent of the GM wheat plants to get as much complete, accurate, and credible information about this discovery as possible. Based on extensive scientific testing, there is no evidence that this GM wheat is present anywhere other than the isolated site where it was discovered.
- There is also no evidence that this wheat has entered the food or animal feed system, nor is it present anywhere else in the environment.
- Health Canada and the CFIA have performed risk assessments of this finding, and have concluded that it does not pose a food safety, animal feed, or environmental risk.
- The wheat plants found in Alberta are not a match for any wheat authorized for sale or for commercial production in Canada.
- The CFIA has developed a test to detect this specific GM wheat, which can be made available to trading partners to test wheat imports, if they choose.
- The CFIA, other federal and provincial partners, and industry representatives were unable to specifically identify the source of the GM wheat. Multi-year monitoring will be conducted and mitigation measures will be adopted at the site to verify that the GM wheat does not persist in the area.

DETECTION AND RESPONSE TO AN ISOLATED CASE OF NON-AUTHORIZED GENETICALLY MODIFIED WHEAT IN CANADA

The Government of Canada has a strong and rigorous regulatory system for GM crops and the foods and animal feeds made from them. As a trusted science-based regulator, the CFIA is committed to being transparent and accountable. This means reporting regulatory non-compliances of interest to the public, industry and trading partners, even when there is no health or safety risk.

This report provides a summary of actions taken by the CFIA and our federal and provincial partners in response to the finding of a small number of herbicide tolerant GM wheat plants on an access road in southern Alberta.

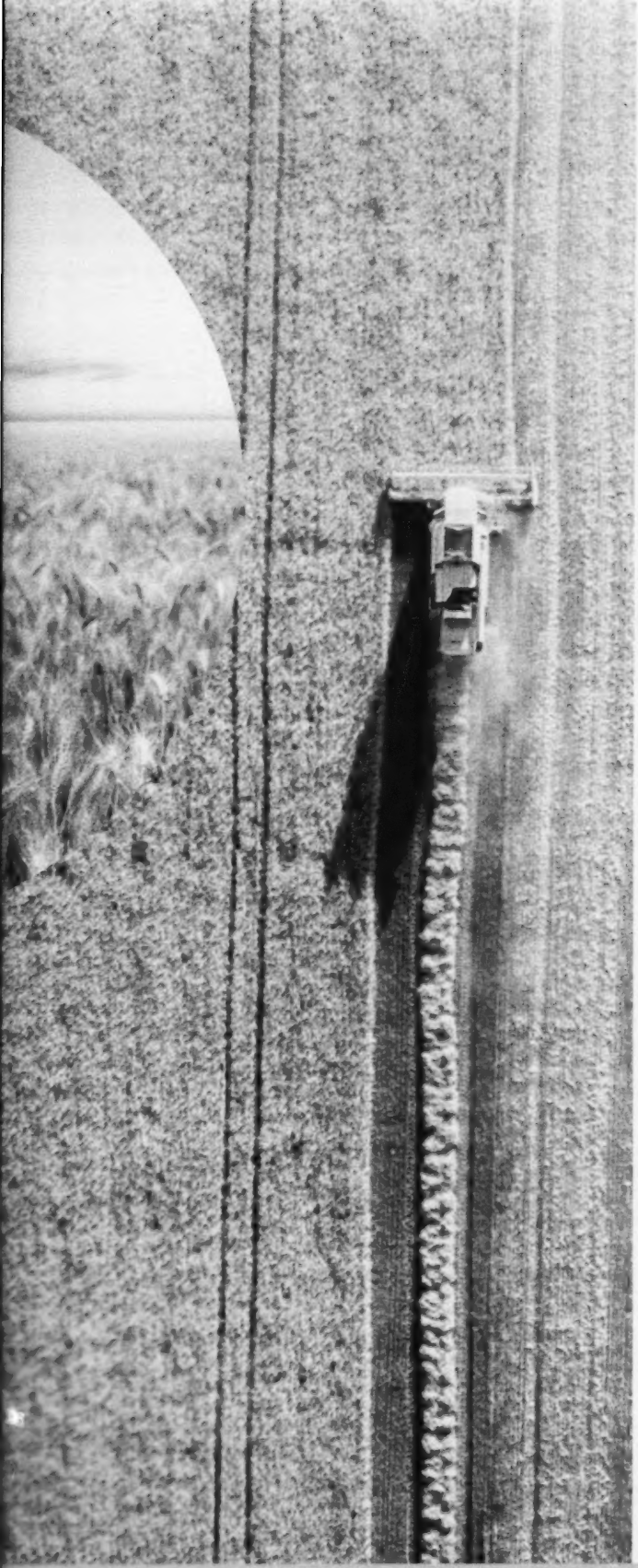


BACKGROUND

The Government of Canada's priority is to protect Canada's environment, animal feed and food systems by using a rigorous scientific approach in assessing safety and managing risk. In Canada, Health Canada and the CFIA are mandated to regulate products of biotechnology, such as GM crops. The CFIA is responsible for regulating the release of GM crops into the environment under the *Seeds Act* and *Seeds Regulations*. The CFIA is also responsible for overseeing the manufacturing, sale and import of livestock feeds including novel feeds under the *Feeds Act* and the *Feeds Regulations*.

Health Canada is responsible for assessing the safety of novel foods for human consumption in Canada under the *Food and Drugs Act* and *Food and Drugs Regulations*.

GM wheat is not authorized in any country for commercial production, as no company has sought commercialization. However, herbicide tolerant GM crops including canola, corn and soybeans have been authorized in Canada for more than 20 years. Assessments by Health Canada and the CFIA have shown that these GM crops are as safe as their non-genetically



modified equivalents and do not pose a risk to human health, the health of animals or the environment. The CFIA's website has a complete list of crops that have been authorized and food safety decisions can also be found on Health Canada's website.

Confined research field trials for GM wheat have been conducted since the 1990s inwheat-growing regions of Canada. Trials have also been conducted around the world in countries including the United Kingdom, United States and Australia. These trials allow information to be gathered on the safety and suitability of the new GM lines for commercial use, which supports economic activity and innovation in Canada's agricultural sector. The CFIA has strict and rigorous conditions for these trials to allow product developers to test their new GM varieties in the field, under conditions of confinement.

All trials are inspected by the CFIA to confirm compliance with these conditions. There have been no cases of any experimental plant material from these trials persisting in the Canadian environment. None of the wheat trials have occurred at or near the location where the GM wheat plants were found, and there is no evidence directly linking the current GM wheat finding with these previously authorized trials. The information on confined research field trials is made public and can be found on the CFIA website.

There have been incidents of unauthorized GM wheat releases in other jurisdictions. The United States reported three separate incidents of unauthorized GM wheat releases which occurred in Oregon in 2013, in Montana in 2014, and in Washington in 2016. These incidents involved GM wheat lines that are genetically different from the

GM wheat found in Alberta. There is no evidence linking Canada's GM wheat finding to previous United States cases. Similar to Canada's finding, GM wheat cases in the United States were isolated incidents, and GM wheat did not enter commerce.

CFIA ACTIVITIES

Discovery and notification

During the 2017 growing season, a herbicide application contractor in southern Alberta reported wheat plants that survived a glyphosate herbicide treatment (Roundup) to local authorities. The Province of Alberta collected samples for testing, and confirmed in late January of 2018 that the wheat was herbicide tolerant.

On January 31, 2018, the CFIA was notified by the Government of Alberta that a few herbicide tolerant wheat plants were found in southern Alberta. The CFIA, in collaboration with federal and provincial partners, immediately undertook comprehensive, risk-based steps to determine the origin and potential extent of these wheat plants.

Confirmation that the herbicide tolerant wheat is genetically modified

On February 12, 2018, the CFIA's Ottawa Genotyping/Botany Laboratory received samples of the wheat seed from Alberta. The CFIA conducted several DNA-based analyses, including polymerase chain reaction (PCR) amplifications of various common GM DNA sequences. This confirmed that the wheat was genetically modified, since it contained pieces of DNA that are known to be used in GM plants and that do not occur naturally in wheat.

In addition to conclusively showing that the wheat was genetically modified, this work helped to exclude certain GM wheat lines from consideration as being the source of the GM wheat in Alberta. The CFIA maintains a database of all GM crops that had been previously planted in confined research field trials in Canada. By determining which specific pieces of engineered DNA were present or absent in the GM wheat, the CFIA was able to narrow down the list of possible GM wheat lines for further testing.

Identification of the genetically modified wheat DNA sequence

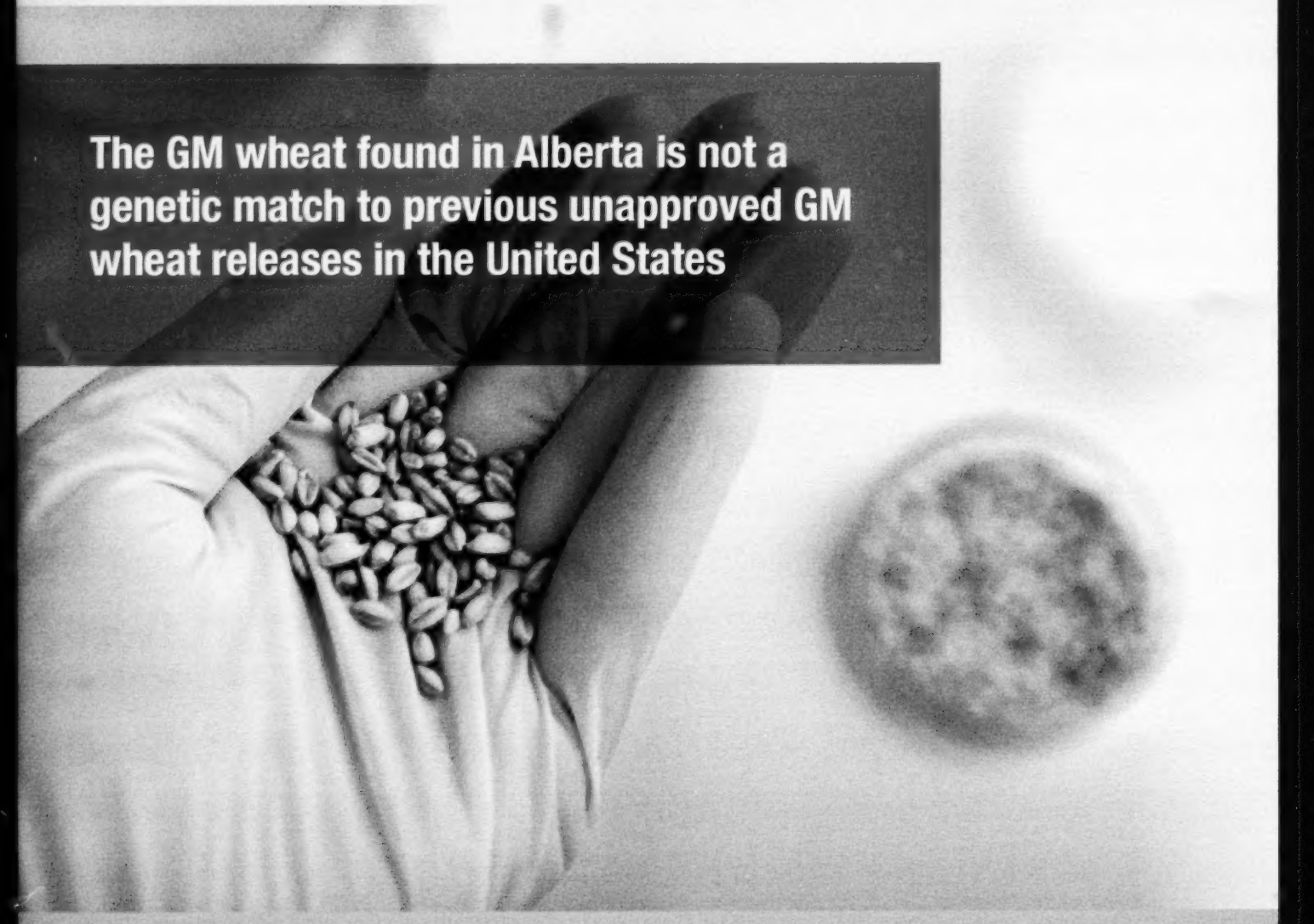
As a result of this analysis, the CFIA was able to focus on a short list of three possibilities belonging to two different companies.
On February 22, 2018, the CFIA contacted both of these companies, who had field-tested GM wheat lines in past trials, to obtain methods and materials for detecting their respective GM wheat lines. Obtaining these materials and methods was important to allow the CFIA to identify the GM wheat.

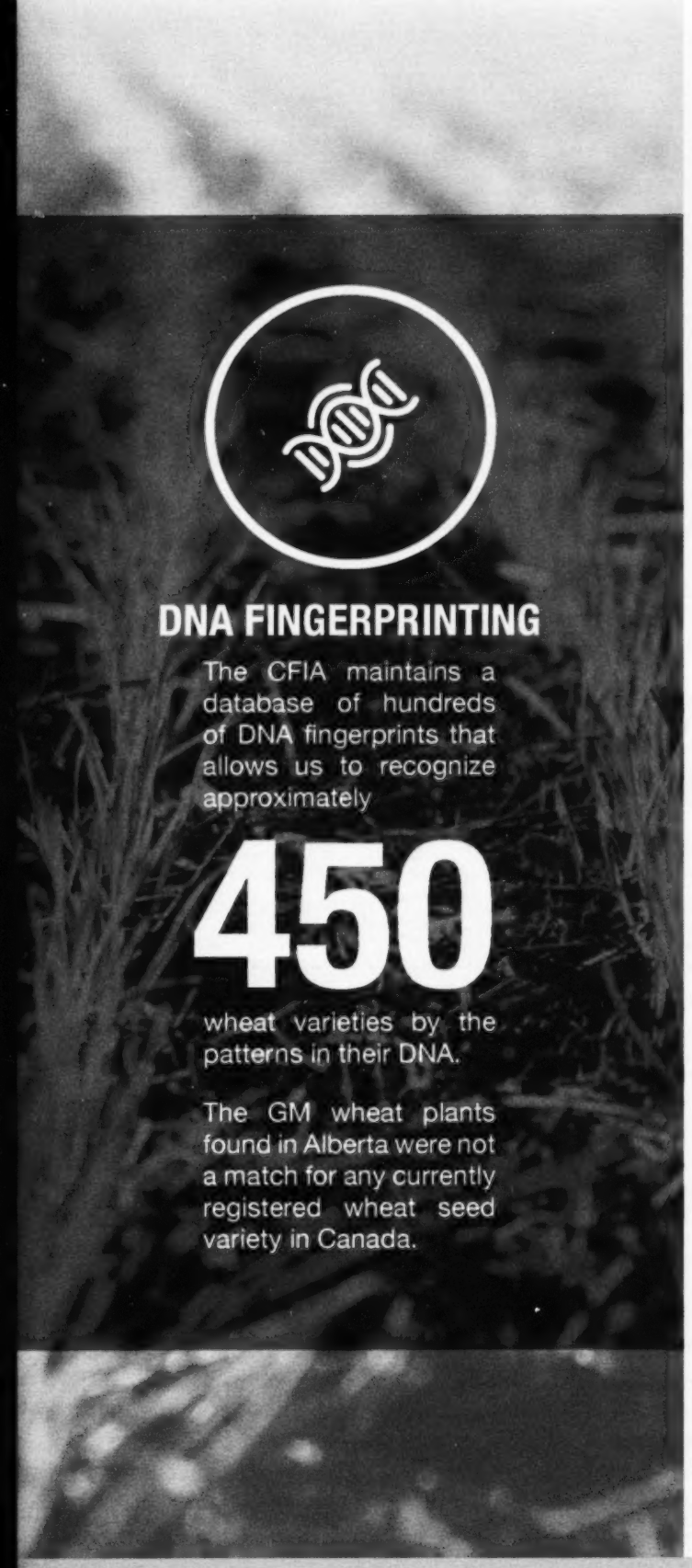
On March 13, 2018, the CFIA was able to eliminate one company's wheat line as the potential source of the GM wheat.
In collaboration with Monsanto, the second company, the CFIA was able to conclusively

determine that the Alberta GM wheat is not a genetic match to previous unapproved GM wheat releases in the United States.

Through further collaboration, on April 8, 2018, the CFIA confirmed that the Alberta wheat sample was a match for a Monsanto GM wheat line (MON71200), which was used in multiple confined research field trials in the late 1990s and early 2000s in both Canada and the United States. The physical locations of the confined research field trials were approximately 300 kilometres or more away from where the GM wheat plants were found in Alberta. Given the passage of time and large distances involved, there is no evidence that would explain how or if the current GM wheat finding is linked with a previous trial.

The GM wheat found in Alberta is not a genetic match to previous unapproved GM wheat releases in the United States





DNA FINGERPRINTING

The CFIA maintains a database of hundreds of DNA fingerprints that allows us to recognize approximately

450

wheat varieties by the patterns in their DNA.

The GM wheat plants found in Alberta were not a match for any currently registered wheat seed variety in Canada.

Background variety identification: providing assurance that Canada's seed and grain is free from GM wheat

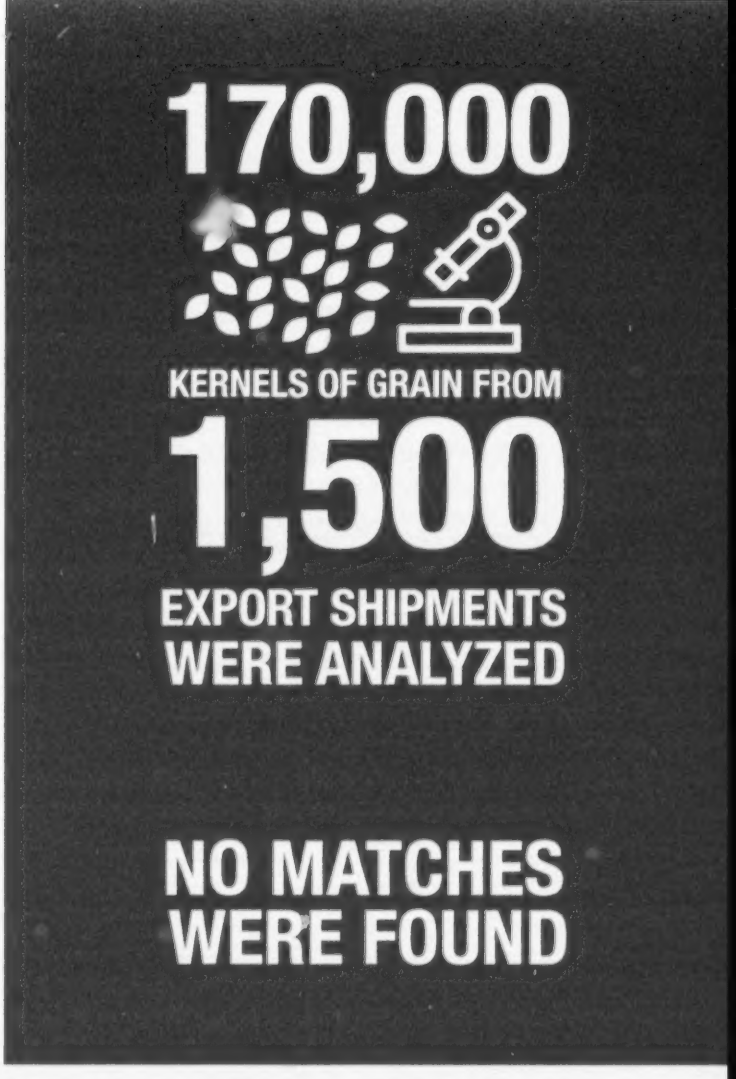
At the same time that the CFIA was working to identify the inserted GM DNA sequence, the CFIA was looking at the rest of the wheat's DNA to learn more about its identity, using a technique known as DNA fingerprinting. DNA fingerprinting functions like a barcode, and allows a living thing to be identified by the unique patterns within its DNA. The CFIA maintains a database of hundreds of DNA fingerprints that allows us to recognize wheat varieties by the patterns in their DNA. The Canadian Grain Commission (CGC) maintains a similar database.

Both the CGC and the CFIA used DNA from the Alberta GM wheat to build a fingerprint and compare it to the fingerprints already stored in these databases. On March 23, 2018, the CFIA, in collaboration with the CGC, confirmed that the GM wheat plants found in Alberta were not a match for any currently registered wheat seed variety in Canada. The GM wheat has a unique DNA fingerprint that does not match any of the approximately 450 wheat varieties on file with the CFIA and the CGC. This means that, as wheat must be registered prior to sale or import into Canada, farmers who purchase registered seed varieties can rest assured that these varieties are free from GM wheat.

The DNA fingerprint was also checked against Canada's grain exports. The CGC samples and monitors all bulk wheat export shipments for quality assurance purposes. Part of this routine monitoring includes verifying the varieties of wheat that are present in a shipment using

DNA fingerprinting. Over the last three crop years, nearly 170,000 individual kernels of grain from more than 1,500 export shipments have been analyzed. Through a review of the data, no matches for this type of GM wheat have ever been found by the CGC. The CFIA will continue to work in collaboration with the CGC to monitor Canadian grain to make sure it does not contain any varieties that do not conform to what should be in bulk export shipments.

To further verify that Canadian grain does not contain any GM wheat, the CFIA and the CGC collaboratively undertook testing of composite wheat samples from the prairie region. On April 9, 2018, the CGC sent five composite wheat samples from its Harvest Sample Program to the CFIA for further analysis. These composite samples are representative of western Canadian wheat classes, and included a total of 1692 individual samples. Both the CFIA and CGC independently tested these samples for GM wheat. On April 26, 2018, the CFIA confirmed that no GM wheat was detected. This result was independently confirmed by the CGC.



Detection method for GM wheat

On April 6, 2018, CFIA finalized the development and validation of a 2-stage PCR-based method to conclusively detect the GM wheat. This method is sensitive enough to detect one GM wheat kernel in 1,000.

The CFIA also sequenced the GM wheat's DNA to learn more about its identity and to begin the development of a second, more efficient 1-stage PCR test to detect this GM wheat. By performing DNA sequencing, the CFIA was able to find where the engineered DNA fragment was inserted into the wheat's DNA. This knowledge formed the basis for developing a PCR-based test that selectively amplifies the DNA sequence at the junction between the natural wheat genome and the inserted engineered DNA. In this way, the test can be performed in a single stage that is highly selective for detecting the presence of the inserted DNA in this GM wheat.

Testing seed and grain from the surrounding area for GM wheat

Having identified the unknown wheat's genetic modification and developed a test to detect it, the CFIA continued to systematically explore leads to determine the source and the potential

1,692 INDIVIDUAL CANADIAN GRAIN SAMPLES WERE TESTED

NO GM WHEAT WAS FOUND

The CFIA will continue to monitor over the next 3 years

extent of the unauthorized GM wheat plants on the access road where they were discovered, and at the farm operation that owns this land.

On April 20, 2018, the CFIA held its first in a series of meetings with the landowner to discuss the history of the land near the access road, the crop rotations on all fields they farm, the agricultural practices on the farm, as well as the location and contents of any materials in storage. The CFIA conducted significant onsite sampling and testing of all wheat stored on the farm and grain that had wheat present. These inspection activities extended to the entire farming operation including nine fields covering approximately 1500 acres of farmed land. All sampling activities of seed and grain were completed based on CFIA's seed sampling protocol that aligns with International Seed Testing Association (ISTA) seed sampling procedures.

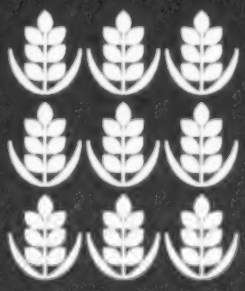
The CFIA was not able to identify anything related to the management practices of the farm that could be linked to GM wheat. The landowner owns and does not share seeding and harvest equipment. The equipment is cleaned in the field or yard and not offsite. All fertilizer and herbicide treatments are done by the landowner using typical application approaches.

This farming operation plants canola, wheat, and barley. All seed samples tested negative for the GM wheat. No seed was ever sold by the landowners. There have been no confined research field trials on the site, or consultants or crop scouts who have visited the farm. All leads were thoroughly explored.

During this same time period, the CFIA also interviewed the lease holders who use the access road. The CFIA was not able to identify anything linking the management of the roadway to the GM wheat. The lease holder confirmed that there has been no construction work done on the road in the last five years. Along the access road, there has been no ground cover seeding of the road ditches and no straw mats were used. Maintenance records for the access road indicate that wheat plants were first identified in 2017 as a weed to be controlled along the road.

On May 1, 2018, CFIA test results for the farming operation's seed and stored grain were all confirmed to be negative for

INSPECTORS SEARCHED A 60,000 M^2 AREA AND COLLECTED 284 WHEAT HEADS



9 FIELDS WERE SAMPLED AND TESTED

THIS COVERED APPROXIMATELY 1,500 ACRES OF FARMED LAND

GM wheat. This finding indicates that GM wheat was not present in the farm's 2017 harvested crops.

On May 8, 2018, as soon as the fields were dry enough, the CFIA conducted additional sampling and testing in the field along the perimeter of the discovery site. The objective was to determine whether the remains of any other GM wheat plants from the previous season were present near the site of the original finding. CFIA inspectors walked a search pattern on both sides of the access road. The access road is 500 metres long, and the search pattern extended 60 metres into the field from each side of the access road. This means that inspectors searched a 60,000 square metre area, collecting all wheat plant remains. A total of 284 wheat heads were found and collected at various distances from the access road and were submitted for testing. On May 23, these samples were confirmed to be negative for the presence of GM wheat, with the exception of 4 wheat heads, which tested positive for the specific GM wheat event (MON71200). These four GM wheat heads were located within a 0-15 metre zone from the access road. This was not surprising, given its proximity to the original find along the access road. This indicates that the GM wheat is present only in a highly localized area.

The CFIA is undertaking multi-year monitoring and the landowner is adopting mitigation measures on the field surrounding the access road to verify that the GM wheat does not persist in the area. These measures include regularly monitoring the site, destroying any wheat that may germinate during the growing season and placing restrictions on the crops that can be grown at this location. The field monitoring will continue throughout the entire growing season, i.e. following snow melt until first frost, for the three growing seasons (2018-2020) following detection. The CFIA will adjust the response and mitigation measures as required based on any potential new findings.

Completion of Risk Assessments

On May 9, 2018, risk assessments examining potential implications of the unauthorized GM wheat to food, animal feed, and the environment were completed by Health Canada and the CFIA. These risk assessments determined that the herbicide tolerant GM wheat does not pose a risk to public health, the health of animals or the environment. GM crops with this herbicide tolerance trait have been authorized in Canada for over 20 years and there have been no human health concerns identified related to these crops.

CONCLUSIONS

After comprehensive testing, analysis and evaluation, the CFIA and other federal and provincial partners, can confirm that no GM wheat has entered the food or feed system, nor is it present anywhere else in the environment. Furthermore, this GM wheat is not a match for any wheat authorized for sale or for commercial production in Canada, demonstrating that Canadian wheat seed is free from GM wheat.

Results from seed and grain samples collected from the farm operation were all negative, meaning no presence of the GM wheat was found. The composite grain samples containing wheat from the discovery site's geographic region tested negative for the presence of GM wheat. Stakeholder interviews and ongoing field monitoring to date point to a highly localized presence of GM wheat along the access road.

Health Canada's food safety risk assessment and the CFIA's animal feed and environmental risk assessments demonstrate that the GM wheat does not pose a food safety risk to the public, an animal feed or environmental risk.

The CFIA in cooperation with other federal, provincial, and industry partners was able to identify the GM wheat and determine the limited scope of its presence, but was unable to specifically identify the source of the GM wheat. All evidence-based lines of inquiry were pursued and have not resulted in any further avenues to be explored. Going forward, the CFIA will focus on monitoring the site and will verify that all GM wheat that may germinate is destroyed.

The CFIA is confident in the results of the extensive testing, but a validated test could be shared with trading partners should they request it.

VISIT WWW.INSPECTION.GC.CA/WHEATDETECTION TO LEARN MORE